Biomechanical properties testing of Maharat Nakhon Ratchasima hospital external fixator system, comparison between the old and new joint designs

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Abstract:

Objectives: To test the biomechanical properties of the old and new joints of Maharat Nakhon Ratchasima hospital external fixator **Methods:** This experimental study used 18 pieces of the right side legs of the pig approximately equal in size, length, width, configuration, without the broken bone. The specimens were randomly allocated into 2 equal groups. All specimens were fixed with the external fixator with the new joint for the first and the old joint designs for the second groups with the control of the point of bone drilling, the perpendicular direction of screw insertion, the depth of screw insertion, the height of the metal rod from the anterior cortex of the bone, the maximal tight of each part of the external fixator, and the point and perpendicular direction of bone cutting at the middle part of pig's tibial bone. All specimens were tested and recorded against the forces in compression, bending and torsion directions. **Results:** In compression and torsion mode, the new joint design tolerated forces lesser than the old one. In bending mode, the new joint design tolerated forces more than the old one. There were no statistically significant differences between the old and new joint designs in any mode of force. **Conclusion:** The old and new joint designs of external fixator system had no statistically significant difference in the biomechanical properties.

Key words: Biomechanical properties, External fixator, New and old joint designs

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บทคัดย่อ: การทดสอบคุณสมบัติทางชีวกลศาสตร์ของเครื่องยึดตรึงกระดูกภายนอกผิวหนัง เปรียบเทียบระหว่างข้อต่อรุ่นเก่าและรุ่นใหม่ ของโรงพยาบาลมหาราชนครราชสีมา

สุรัตน์ ส่งวิรุฬห์ พ.บ.*,
สมชัย เชื่อมกลาง**
* กลุ่มงานศัลยกรรมออร์โธปิดิกส์, โรงพยาบาลมหาราชนครราชสีมา จ.นครราชสีมา
** ช่างเครื่องช่วยคนพิการ หน่วยกายอุปกรณ์ กลุ่มงานเวชกรรมฟื้นฟู, โรงพยาบาลมหาราชนครราชสีมา จ.นครราชสีมา
เวชสารโรงพยาบาลมหาราชนครราชสีมา 2560; 39: 141-6.

วัตถุประสงค์: เพื่อทดสอบคุณสมบัติทางชีวกลศาสตร์ของเครื่องยึดตรึงกระดูกภายนอกผิวหนัง เปรียบเทียบระหว่างข้อต่อรุ่นเก่าและรุ่นใหม่ของโรงพยาบาลมหาราชนครราชสีมา **วิธีการ:** การศึกษาทดลองครั้งนี้ใช้ขาหลังข้างขวาของหมูในการทดสอบจำนวน 18 ชิ้น โดยสุ่มคัดเลือกให้มีขนาดความยาว ความกว้าง รูปร่างไม่บิ่นหรือแตก แบ่งแบบสุ่มเป็น 2 กลุ่ม ๆ ละ 9 ชิ้นเท่ากัน ทุกชิ้นได้รับการยึดตรึงด้วยเครื่องยึดตรึงกระดูก ภายนอกผิวหนัง โดยกลุ่มแรกใช้ข้อต่อรุ่นใหม่ และอีกกลุ่มใช้ข้อต่อรุ่นเก่า โดยควบคุมตำแหน่งเจาะรูกระดูก ทิศทางตั้งฉากในการเจาะรูกระดูก ความลึกในการใส่แท่งเหล็ก ความสูงของแกนยึดแท่งเหล็กกับขอบกระดูก แรงบิดสูงสุดในการยึด ส่วนประกอบตำแหน่งกลางขา และทิศทางตั้งฉากของการตัดกระดูกเป็นสองท่อน ทั้งสองกลุ่มถูกนำไปทดสอบ และบันทึกคุณสมบัติทางชีวกลศาสตร์ในแนวแรงกด แรงหักงอ และแรงบิดหมุน **ผลการศึกษา:** ในแนวแรงกด และแรงบิดหมุน ข้อต่อรุ่นใหม่สามารถทนแรงได้น้อยกว่าข้อต่อรุ่นเก่า ในขณะที่ในแนวแรงหักงอ ข้อต่อรุ่นใหม่ สามารถทนแรงได้มากกว่าข้อต่อรุ่นเก่า โดยที่ไม่มีความแตกต่าง อย่างมีนัยสำคัญทางสถิติในทุกแนวแรงระหว่างข้อต่อรุ่นใหม่และรุ่นเก่า
คำสำคัญ: คุณสมบัติทางชีวกลศาสตร์, เครื่องยึดตรึงกระดูกภายนอกผิวหนัง, ข้อต่อรุ่นใหม่และรุ่นเก่า

Introduction

An external fixator is one of medical instruments which consists of a metal rod, joint and screw connected to bone. It is used to initially stabilize the bone outside the skin for treating the fracture with the lacerated wound which is diagnosed as the open fracture and waited for definite treatment after the wound is healed to decrease the risk of infection(1-5). This instrument is originally manufactured in foreign countries with high cost but no information about the biomechanical properties described because of the commercial benefit.

The Body Equipment Division, Department of Physical Medicine and Rehabilitation, Maharat Nakhon Ratchasima Hospital has produced the medical grade metal steel 316 L external fixators which do not become rusty for use in the patients at our own and other hospitals all over Thailand for more than 30 years. They are much cheaper than those bought from foreign countries. Nevertheless, there are 3 points of limitation for insertion in the patients. First, they have 2 dimensions in axis, not 3 dimensions which may be more suitable and more adjustable for any direction of application of the instruments. Second, the bone must be drilled with the perpendicular direction to apply the screw which may be less flexible for the application. Third, the young orthopedic staff or residents who have not much experience may have some difficulty to apply them and spend more time to operate the patients particularly in cases with severely comminuted fracture of bone. Although the external fixators produced in our hospital have been used for many years in the patients but they have never been tested for the biomechanical properties to know how strong they are to resist the compression, bending and torsion forces.

We analyzed the limitations and designed the new joint of the external fixator to lessen such limitations. They were designed to increase the screw inclination in the bone to 20 degrees in the sagittal plane on each side and overall could be 40 degrees to have more flexibility for application. This new joint design might help the young orthopedic staff or residents can more easily apply the external fixator and save the operation time for the patients too.

Objectives of the study

1. To design the new joint of the Maharat Nakhon Ratchasima hospital external fixator to have more flexibility for application
2. To test the biomechanical properties of the external fixator with the experimental randomized trial comparison between the old and new joint designs
3. To find the basic information of the external fixator for more development in the future

Methods

1. By using the tibial bone of the right hind leg of the pig instead of human's tibia for the ethical reasons and avoidance of difficult collection of the human bone. The whole soft tissue was completely resected until the clear bone was achieved. All 36 pieces were collected but only 18 pieces of them which had approximately equal size, length, width, configu-ration, and no broken piece of bone, were recruited for testing.
2. Each specimen was randomly allocated into 2 groups, 9 specimens in each group. One group was applied with the new joint design and the other group with the old joint design of the external fixators.
3. All specimens of both groups were applied with the external fixator with the control of the point of bone drilling, perpendicular direction of screw insertion, depth of screw insertion, height of the metal rod from the anterior cortex of the bone, maximal tight of the fixation of the external fixator, point and perpendicular direction of bone cutting at the middle part of pig's tibial bone to mimic the condition of clinical fracture. All of these were designed to control all the factors which might disturb the results of the test. All the specimens were packed into the ice box for the test on the following day.

Figure 1 The Old (Left) and New (Right) joint designs of the external fixator

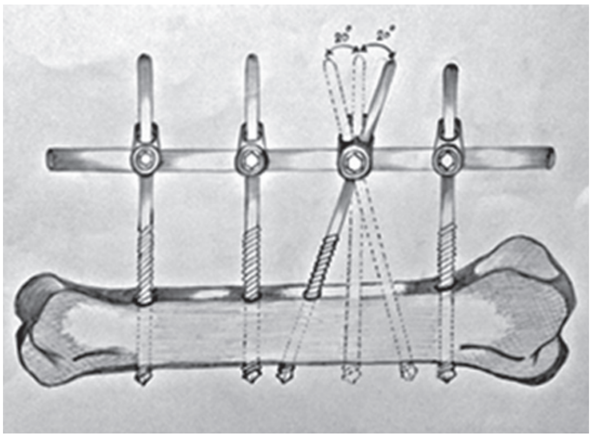

Figure 2 Show new joint design which could apply more inclination to 40 degrees instead of perpendicular direction in old joint design

Figure 4 The compression mode test machine and the specimen

4. All specimens were tested to record how much strength they could tolerate in any direction of forces, compression, bending and torsion. The machines belonged to the center for scientific and technological equipment, Suranaree University of Technology. And also the experimental processes were performed at this center.

5. All specimens of the first group were ran-domly selected to test the tolerance in compression, bending and torsion forces, 3 specimens for each force. The same maneuver was performed for the latter group also. The machines would be stopped and the results were recorded after the bones were broken or displaced from the initial alignment. All the result data were collected for statistical analysis.

Discussion

The table 1 shows the results of the forces that the specimens in both groups using the old and new joint designs could tolerate in any direction of forces; compression, bending and torsion. In compression and torsion modes, the new joint design external fixator

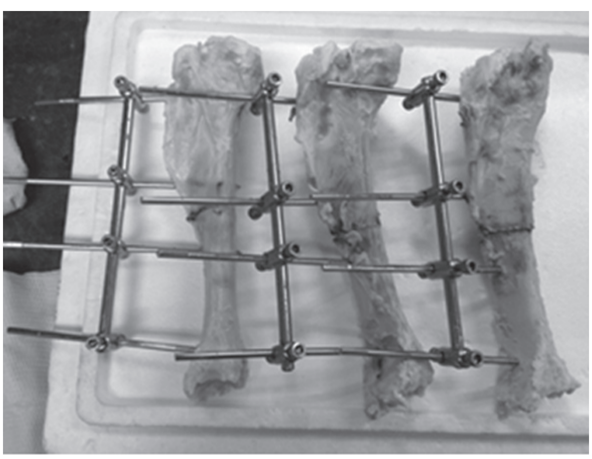

Figure 3 Examples of the test specimens

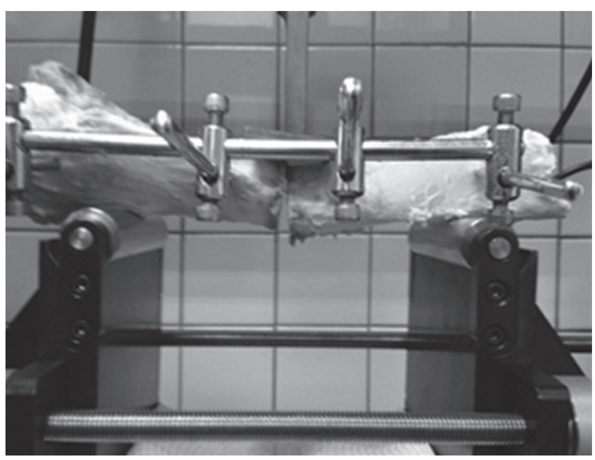

Figure 5 The bending mode test machine and the specimen

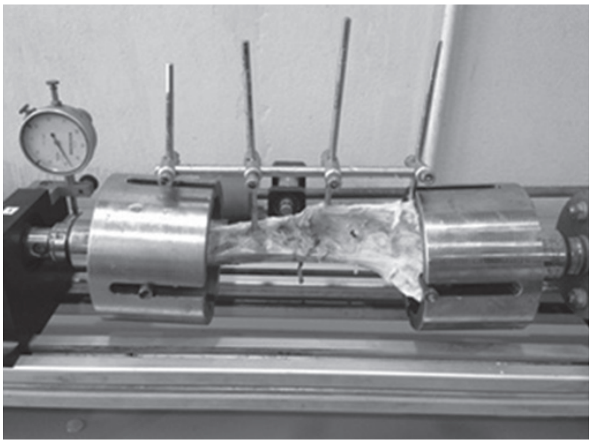

Figure 6 The torsion mode test machine and the specimen

can tolerate forces less than the old one. On contrary, the new joint design external fixator can tolerate forces more than the old one in the bending mode. However the differences between the old and new joint designs have no statistical significance in every mode of force. The standard deviation in compression mode test may be high probably because of too few specimens tested.

The tibial bones of the right hind legs of the pig and the number of the specimens used in this experiment in each force and group were advised by the orthopedic professor at the medical faculty and by the staff from the center for scientific and technological equipment, Suranaree University of Technology that their bony configuration and biological properties resemble the human bone.

The authors accept that the pig's legs were natural animal bones so all specimens could not be homogeneously similar in all dimensions. So, the authors designed the study using the randomization and the control in every step about the pig's bone specimens to minimize these effects. The number of specimens tested in any force and any group may interfere also. They would be more accurate if more specimens were used in the study. Another way to get better and more accuracy of the specimens is to use the plastic pipeline instead of pig's bone.

This experiment was the pilot study to test the strength of the new design joint of external fixator to tolerate the forces. They were applied in the perpen-dicular direction of the screw to the bone and showed no statistically significant differences between the old and new joint design in any force. There should be another study designed to test what biomechanical properties would be if the screw are placed with the inclination 20 degrees on each sides of the fracture, the new joint designed for more flexibility and easier insertion of the external fixator system. If the new design study also shows good results, it should be further approved in patients as the clinical trial if it will be approved by the medical ethic committee of the hospital.

Table 1 Results of the biomechanical test of the specimens

Force	Joint design	Mean (Newton-Meters)	Standard deviation	P-value
Compression	Old	11,154.13	6,720.52	0.6679
	New	8,827.03	5,556.82	
Bending	Old	21.44	2.34	0.0547
	New	34.71	8.22	
Torsion	Old	6.19	1.67	0.3061
	New	4.77	1.27	

The authors declare to commit the copyright of the ideas, knowledge or future development about this new joint design of external fixator system belongs to Maharat Nakhon Ratchasima Hospital. Any person or company that is not permitted to use this design or knowledge will be defined as infringe the copyright from the hospital.

Conclusion

The old and new joint designs of the external fixator have no statistically significant differences of the biomechanical properties in the test.

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